

Mitchell E. Daniels, Jr. Governor

Gregory N. Larkin, M.D., F.A.A.F.P. State Health Commissioner

DATE:

October 12, 2010

TIC

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS

Director, Food Protection Program

SUBJECT:

FDA News Release Slimming Capsules

SUGGESTED

ACTION: FDA Advisory; FDA warns that Slimming Beauty Bitter Orange Slimming Capsules

contain the active pharmaceutical ingredient sibutramine, a prescription-only drug which is a stimulant. Sibutramine is not listed on the product label and could harm consumers, especially those with cardiovascular conditions; Information provided in

case of consumer inquiry.

FDA NEWS RELEASE

For Immediate Release: October 8, 2010

Media Inquiries: Elaine Gansz Bobo, 301-796-7567, elaine.bobo@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA: Potentially harmful stimulant found in Slimming Beauty capsules

'All natural' products contain controlled substance sibutramine

The U.S. Food and Drug Administration today advised consumers who have Slimming Beauty Bitter Orange Slimming Capsules not to use the product. FDA warns that Slimming Beauty Bitter Orange Slimming Capsules contain the active pharmaceutical ingredient sibutramine, a prescription-only drug which is a stimulant. Sibutramine is not listed on the product label and could harm consumers, especially those with cardiovascular conditions.

FDA lab tests reveal that the product contains excessive amounts of sibutramine that may be dangerous to people who have a history of cardiovascular disease, because it can lead to elevated blood pressure, stroke, and heart attack.

Consumers who are otherwise healthy and who take the amount of sibutramine found in Slimming Beauty capsules can experience anxiety, nausea, heart palpitations, a racing heart, insomnia, and elevated blood pressure. Sibutramine also may interact with other medications and can cause serious side effects.

Sibutramine is a powerful stimulant that should not be used without a prescription due to the safety risks associated with it.

Slimming Beauty is being sold over the Internet by Beautiful Health Inc., formerly LL Health and Beauty. Slimming Beauty sample packets also have been distributed by individuals at community events. The product and the sample packets are falsely labeled as "100% Herbal." The sample packet label is misleading because it indicates that it is a natural vitamin and calcium capsule for use in children as young as 2 years old.

The FDA has determined that Slimming Beauty sample packets were distributed at the 40th Annual Mexican Independence Day Parade in Chicago, on Sept. 12, 2010. The agency is aware of several reports of serious side effects from the use of this product including elevated blood pressure, headaches, vomiting, and insomnia.

Consumers and health care professionals are encouraged to report adverse events related to the use of Slimming Beauty capsules to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.htm or by phone at 800-FDA-1088 (800-332-1088).

Sample packets contain four capsules in a small, clear, plastic bag stapled to Slimming Beauty advertising material written in Spanish.

For more information:

FDA Drug Safety and Availability Web Page http://www.fda.gov/Drugs/DrugSafety/default.htm